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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,765	01/05/2004	Pierluca Lombardi	03-728	2275
34704            7590            02/14/2007 BACHMAN & LAPOINTE, P.C. 900 CHAPEL STREET SUITE 1201 NEW HAVEN, CT 06510			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3767	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/14/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/751,765	LOMBARDI, PIERLUCA
	Examiner Andrew M. Gilbert	Art Unit 3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 December 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 19 and 20 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 13-16, 18 and 21-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 January 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### ***Acknowledgments***

1. This office action is in response to the reply filed on 12/4/2006.
2. In the reply, the Applicant amended claims 13, 18, and 21; cancelled claim 17; and added new claims 23 and 24.
3. Additionally, the Applicant submitted formal drawings (see below).

### ***Election/Restrictions***

4. The Applicant argued that claim 19 was improperly restricted in the previous office action because the Examiner never asserted a restriction requirement against claim 19. This is not persuasive because the Applicant required an election of species in the Election/Restriction requirement mailed on 4/6/2006 and in response the Applicant elected Species II: Figure 3. Claim 19 reads on Species III: Figs 4-6 wherein the pressure-operated valve is adapted to release negative pressure from the housing and the threshold is a maximum negative pressure (see paragraph 35 of the Applicant's specification) and does not read on Species II: Fig 3. Thus, claim 19 remains withdrawn. The election/restriction requirement is found to be proper and is made final.
5. Thus, claims 13-16, 18, 21-24 are pending for examination.

### ***Drawings***

6. The drawings are objected to because they do not denote the newly submitted drawings as either "**Replacement Sheet**" or "**New Sheet**" pursuant to 37 CFR 1.121(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

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replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "**Replacement Sheet**" or "**New Sheet**" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 12-16, 18, 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Binard et al (4403988). Binard et al discloses an apparatus for regulating pressure applied during a medical procedure, comprising: an inelastic housing (50) enclosing an inner volume, the housing having a first and second end (Fig 9); an aperture (52) in the housing for conveying pressure from the housing during medical

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procedure, and a pressure-operated valve (64) coupled between the inner volume of the housing and a space outside of the inner volume of the housing for allowing pressure to escape from the inner volume of the housing through the valve when pressure in the housing exceeds a threshold, whereby the valve releases pressure from within the inner volume of the housing (col 5, Ins 30-64); wherein the pressure-operated valve is adapted to allow selection of the threshold from a plurality of different thresholds (col 2, Ins 5-8; col 5, Ins 30-64; wherein the Examiner notes that the user can select from a plurality of springs to selected a desired threshold release pressure); wherein the housing is a cylindrical inelastic housing enclosing the inner volume (Fig 11); wherein the pressure-operated valve comprises: an opening (66) in the housing; a plunger (68) disposed within the inner volume of the housing; a spring (74) disposed within the inner volume of the housing, wherein the spring is positioned between the second end of the housing and the plunger (Fig 9), wherein the plunger in a rest position is between the opening and the aperture (Fig 9), and wherein as fluid is inserted into the inner volume of the housing via the aperture (col 5, Ins 30-64), increased pressure within the inner volume of the housing moves the plunger toward the opening (Fig 10); wherein the opening is positioned in a side of the housing (Figs 9-10) providing access to the inner volume the housing, wherein at normal pressure the opening is closer to the second end than the plunger and wherein as pressure within the inner volume of the housing increases so as to move the plunger past the opening (Fig 10), the pressure within the inner housing is released through the opening; wherein a plurality of openings (82, 84a, 84b) are positioned along the housing, and further comprising a selector member (68)

movably mounted relative to the plurality of openings and positionable so as to selectively open one and block others of the plurality of openings (Figs 9-10); a pressure operated valve communicated with the inner volume of the housing and adapted to release pressure from the inner volume when pressure in the inner volume is above a threshold (col 5, Ins 30-64); wherein the housing is a syringe (22; Figs 1-20) comprising a substantially inelastic housing enclosing the inner volume and a plunger within the inelastic housing; wherein the threshold is set by a spring exerting a force which must be overcome to exceed the threshold (col 2, Ins 5-8; col 5, Ins 30-64; Figs 9-10; wherein the Examiner notes that the user can select from a plurality of springs to selected a desired threshold release pressure), and further comprising a movable member (80) which can be positioned between at least two different positions corresponding to different forces of the spring which must be overcome to exceed the threshold (80, Figs 9-10; wherein the Examiner notes that the movable member (80) can be position between at least two different positions, such as the position where the movable member is just forced enough to separate from (70) and allow initial release of pressure and the position where the movable member is forced fully open and is maximally open, each of which correspond to different forces of the spring that must be overcome to exceed the threshold).

***Response to Arguments***

9. Applicant's arguments filed 12/4/2006 have been fully considered but they are not persuasive.

10. The Applicant argues that:

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i. Binard et al does not teach a valve to be adapted to allow selection of the threshold from a plurality of different thresholds (Remarks, pg 12, paragraphs 3-5)

11. In response to applicant's argument (i) that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a movable member can be positioned to different locations where different forces on the spring are needed to release pressure and that the selection of the threshold from a plurality of thresholds is performed during use) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the instant case, the Examiner refers the Applicant to col 2, Ins 5-8; col 5, Ins 30-64 and notes that the user can select from a plurality of springs to selected a desired threshold release pressure. The Examiner suggests adding the limitation "in use" or "during use" to overcome the prior art and further specify that the threshold can be selected and changed during use of the medical device. Furthermore, in reference to claims 23 and 24 the Examiner refers the Applicant to (80), Figs 9-10 and notes that the movable member (80) can be position between at least two different positions, such as the position where the movable member is just forced enough to separate from (70) and allow initial release of pressure and the position where the movable member is forced fully open and is maximally open, each of which correspond to different forces of the spring that must be overcome to exceed the threshold). The Applicant has not required that these when at the different locations the

movable member prevents release of pressure when the force on the springs correspond to the other locations. The Examiner suggests further structurally defining the movable member and distinguishing that the when movable member is at a position, the movable member causes pressure only to be released once that corresponding spring force is exceeded.

***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Andrew Gilbert

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

